

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

WYETH,

Plaintiff,

v.

IMPAX LABORATORIES, INC.,

Defendant.

Civil Action No. 06-222 (JJF)

**IMPAX'S RESPONSE TO WYETH'S CITATION OF  
SUBSEQUENT AUTHORITY IN SUPPORT OF ITS MARKMAN BRIEFING**

Impax files this response to Wyeth's Citation of Subsequent Authority in Support of its Markman Briefing. (D.I. 221). Wyeth cites *Saunders Group, Inc. v. Comfortrac, Inc.*, No. 2006-1576, a June 27, 2007 Federal Circuit opinion, in support of its proposed construction of "extended release formulations." The *Saunders* opinion reaffirms the same claim construction principles discussed at length by Impax in its Markman briefing and during oral argument.

In *Saunders*, the Federal Circuit reversed a construction of "pneumatic cylinder" that limited the term to cylinders containing at least one pressure activated seal. (D.I. 221-2 (Ex. A to Wyeth's Citation of Subsequent Authority, Slip. Op. at 4 (hereinafter "Slip. Op.")).) The Federal Circuit reached that conclusion for three reasons.

**First**, the Federal Circuit noted the specification did not expressly state that a pressure activated seal was an essential component of the invention. Slip. Op. at 9. Instead, the district court inferred such a requirement in part because the only disclosed embodiment of the pneumatic cylinder contained such a seal and because a broad construction would render the patent invalid for lack of enablement. The *Saunders*' patent specification indicated only that pneumatic cylinders "typically" would not perform the

necessary function, but not that the invention was impossible without using a pressure activated seal. Slip. Op. at 9-10.

The Federal Circuit distinguished *Alloc, Inc. v. International Trade Commission*, 342 F.3d 1361 (Fed. Cir. 2003), because there the specification specifically taught that the limiting feature was necessary and the invention was impossible without it. Ex. A at col. 1:40-44 (U.S. Pat. No. 6,899,690).

Here, as in *Alloc*, the specification of the patents in suit repeatedly describes “the invention” as a formulation comprising venlafaxine, MCC, and, optionally, HPMC. (D.I. 162 at 13, citing *Alloc, Inc.*, 342 F.3d at 1368-69)). The specification recites the patentees’ failed attempts at developing other formulations. *Id.* The patentees explicitly defined their invention as a specific formulation. Impax is not asking the court to adapt a narrow construction in order to preserve the validity of the claims. Instead, Impax is asking the Court to construe the claim scope consistent with the patentees’ description of their invention.

**Second**, considering the text of two asserted claims, the *Saunders* court found that the presumption of claim differentiation weighed against the narrower construction and that defendants failed to identify evidence rebutting that presumption. Slip. Op. at 7. Here, the *Teva* court correctly determined that this presumption was overcome by the patentees’ having defined the term “extended release formulation” through their repeated statements that “the invention comprises an extended release formulation of”, “[t]he formulations of this invention comprise” and “[t]he extended formulations of this invention are” specific ingredients. (D.I. 190 at 11-12).

**Third**, the *Saunders* court found that the prosecution history also weighed against a narrow construction, noting that in the Petition to Make Special the applicant accused devices lacking a pressure activated seal. Slip. Op. at 7. In contrast, during the prosecution history of the asserted patents Wyeth acquiesced to a narrower claim scope by agreeing to narrow its claims and did not expressly rescind that acquiescence by directing the examiner to reconsider the relevance of the prior art that had resulted in the earlier rejection. (D.I. 162 at 16-17 and D.I. 190 at 15-17).

Dated: July 12, 2007



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# EXHIBIT A

(12) **United States Patent**  
**Saunders et al.**

(10) **Patent No.: US 6,899,690 B2**  
(45) **Date of Patent: \*May 31, 2005**

(54) **PORTABLE CERVICAL TRACTION DEVICE**

**FOREIGN PATENT DOCUMENTS**

(75) Inventors: **H. Duane Saunders**, Eden Prairie, MN (US); **Mark R. Stultz**, Minnetonka, MN (US)

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(73) Assignee: **The Saunders Group, Inc.**, Chaska, MN (US)

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(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 103 days.

Glacier Cross, Inc. product brochure, PRONEX™, "A patient-controlled pneumatic device for the comfortable and secure management of cervical pain," 2 pp., undated.

Zinco Industries, Inc. product brochure, Pneu-trac™, "Air Pressure the Patient Controls," 1 p., undated.

"Spinal Traction," *Evaluation, Treatment and Prevention of Musculoskeletal Disorders*, Chapter 10, pp. 275-302, undated.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **10/320,589**

(Continued)

(22) Filed: **Dec. 16, 2002**

(65) **Prior Publication Data**

US 2003/0088200 A1 May 8, 2003

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**Related U.S. Application Data**

(57) **ABSTRACT**

(63) Continuation of application No. 08/817,444, filed on Oct. 22, 1997, now Pat. No. 6,506,174, which is a continuation of application No. PCT/US95/14217, filed on Oct. 31, 1995, which is a continuation-in-part of application No. 08/334,189, filed on Nov. 3, 1994, now abandoned.

A portable traction device suitable for cervical traction powered by a pneumatic cylinder. The portable traction device includes a support structure having a longitudinal axis and a carriage slidable along a portion of the support structure parallel to the longitudinal axis. The carriage including restraining mechanism for releasably restraining a portion of a patient's body to the carriage. A pneumatic cylinder includes a cylinder housing attached to the support structure. The cylinder housing contains a piston and piston rod. The piston rod is attached to the carriage for moving the carriage along the longitudinal axis relative to the support structure when pressurized air is injected into the pneumatic cylinder. The piston has at least one pressure activated seal extending circumferentially around the piston for engagement with an inside surface of the cylinder housing. A bicycle-style hand pump fluidly connected to the pneumatic cylinder is provided for injecting pressurized air into the cylinder.

(51) **Int. Cl.**<sup>7</sup> ..... **A61F 5/00**

(52) **U.S. Cl.** ..... **602/36; 602/32; 602/33; 602/18**

(58) **Field of Search** ..... 602/32, 33, 35, 602/36, 18; 128/845, 846, 869, 870

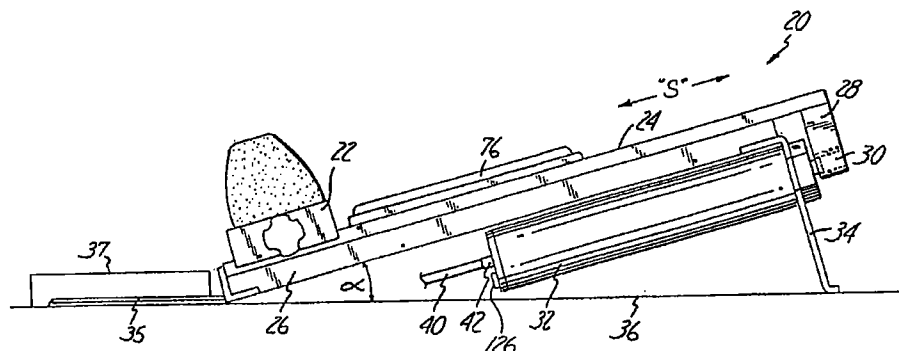
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**21 Claims, 10 Drawing Sheets**



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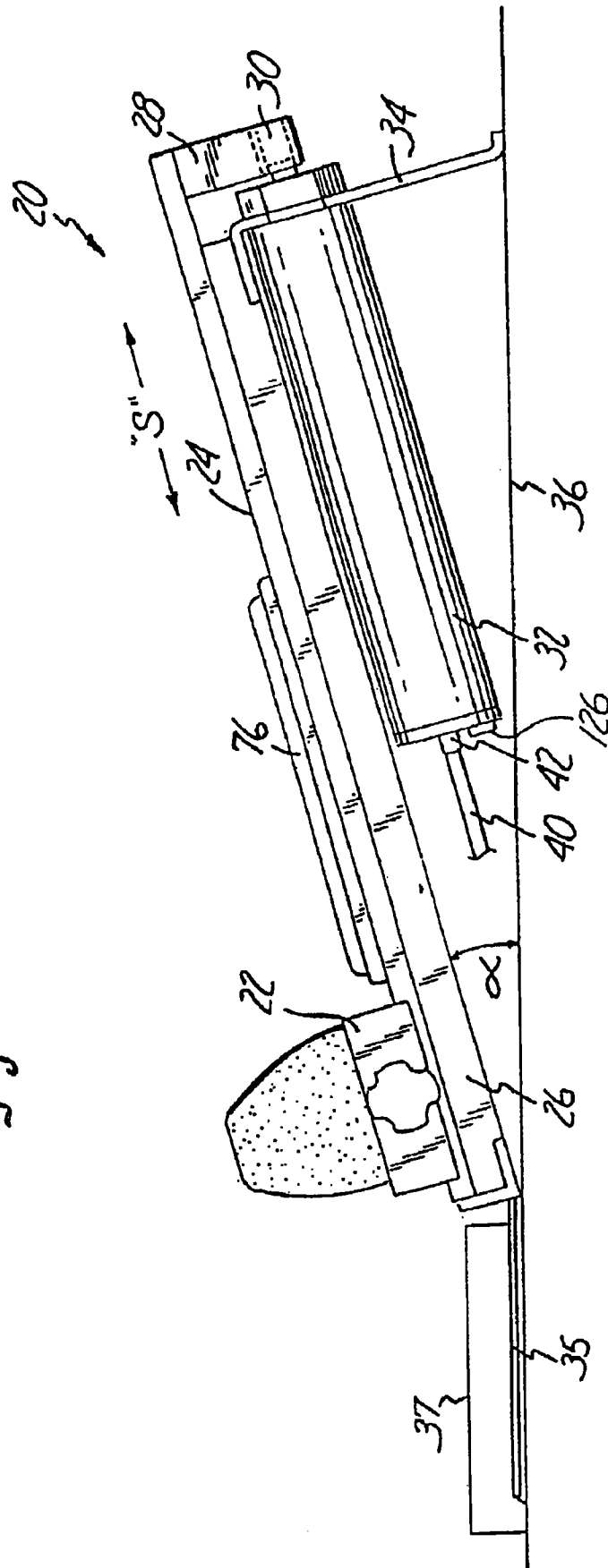
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Fig. 1

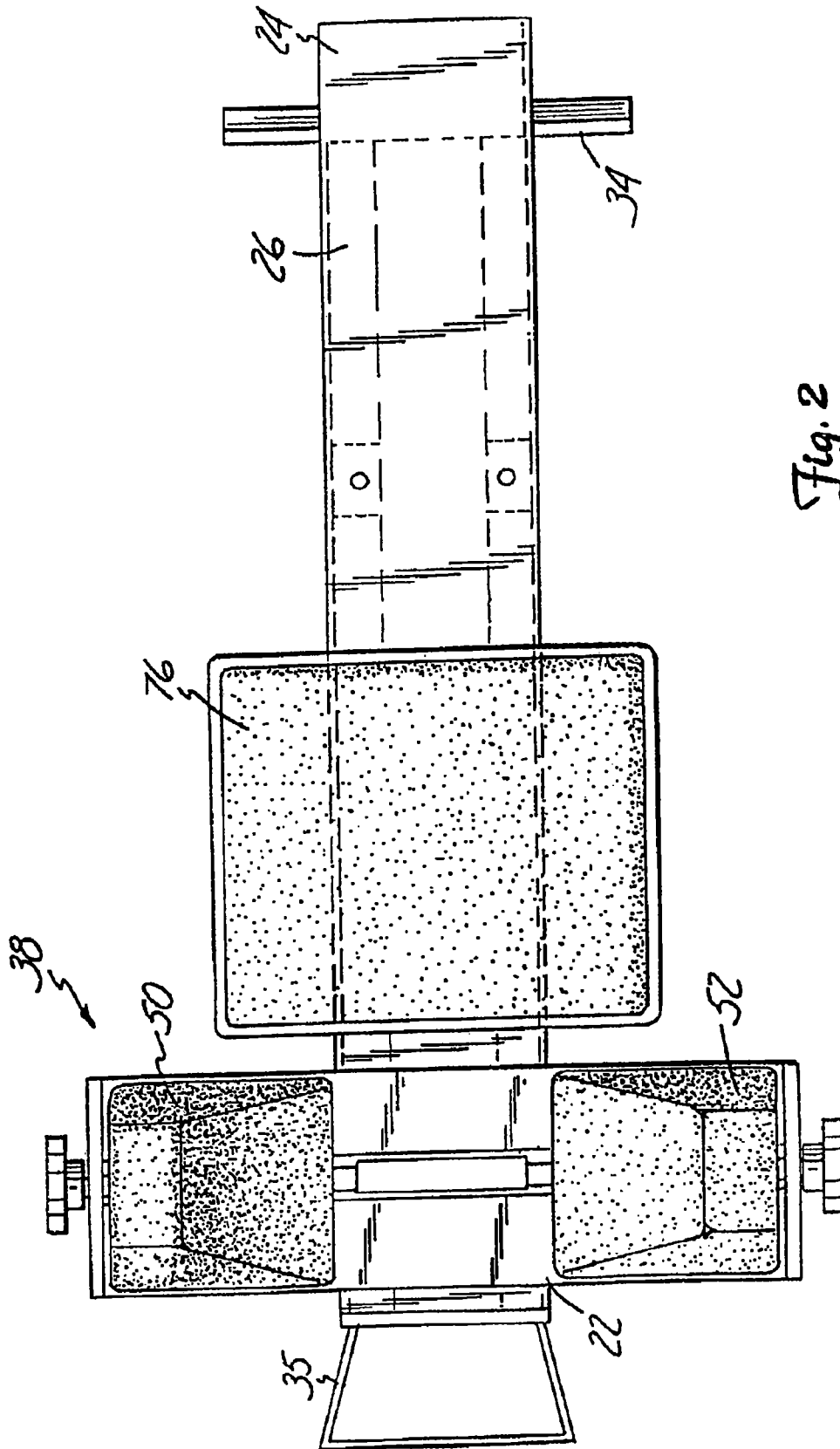


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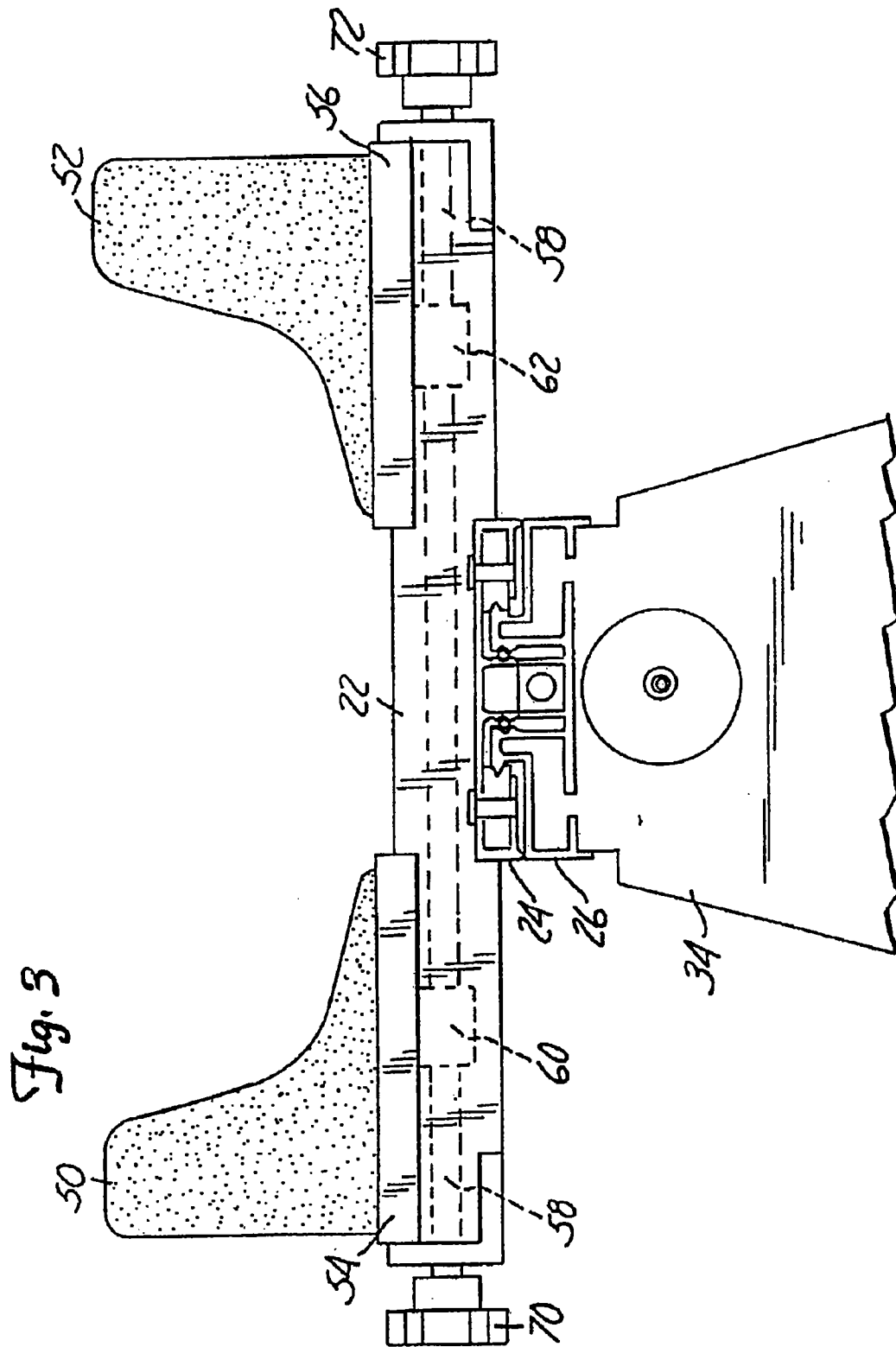


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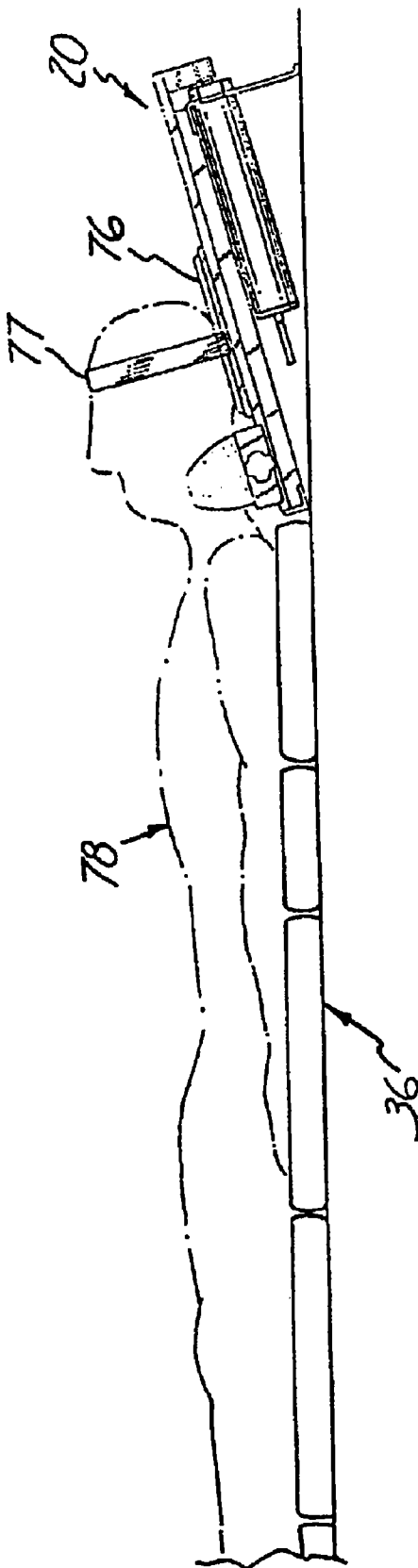
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Fig. 4

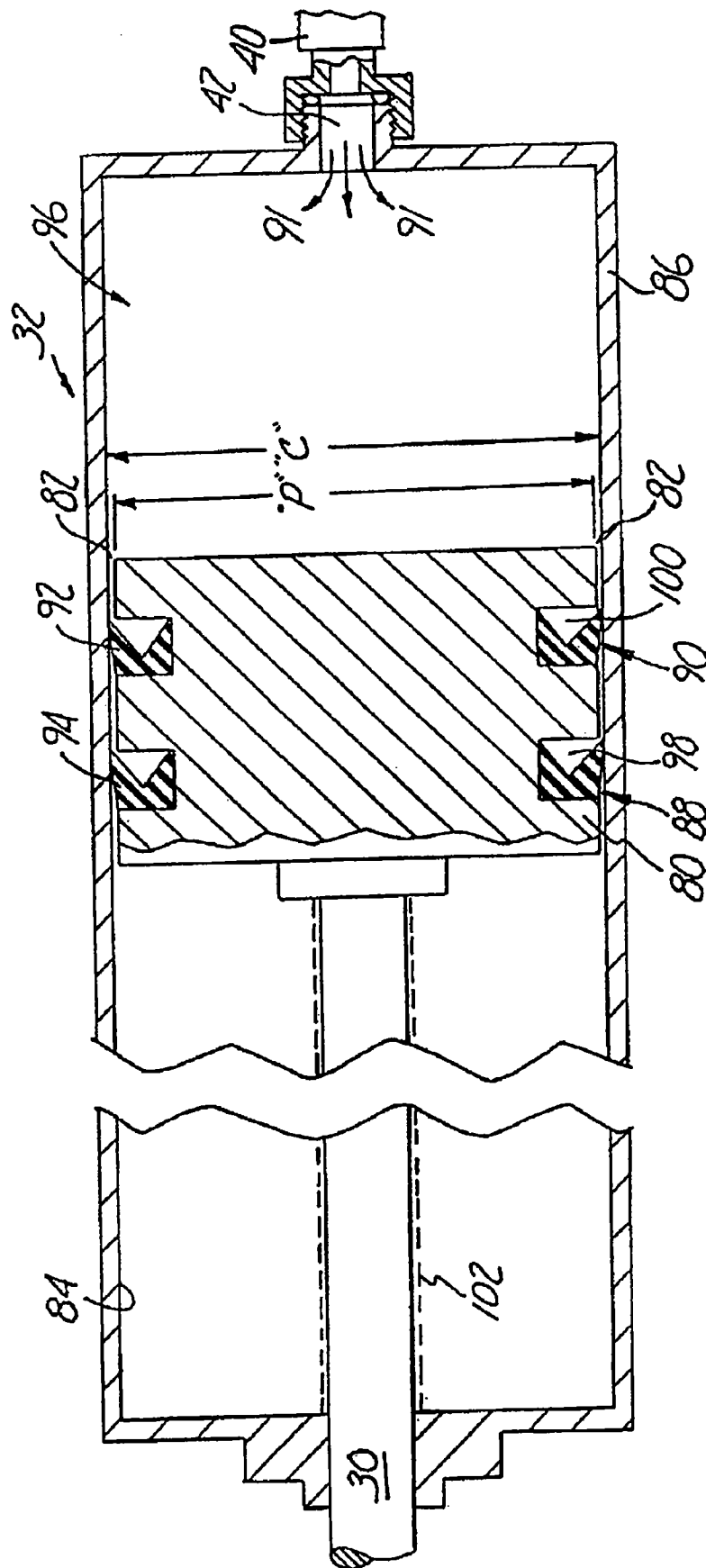


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*Fig. 5*

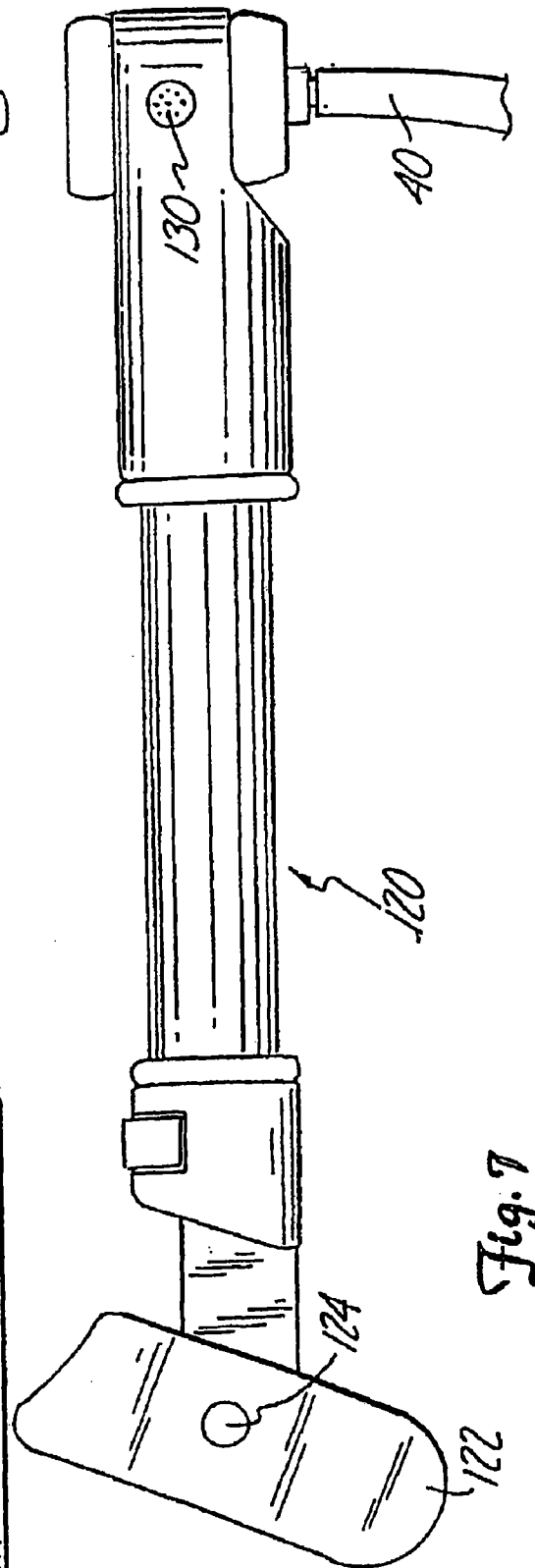
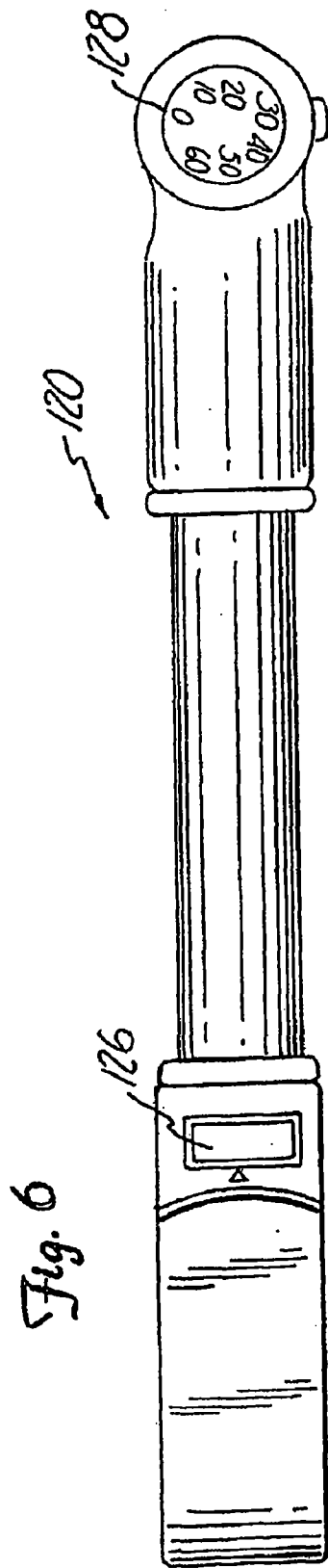


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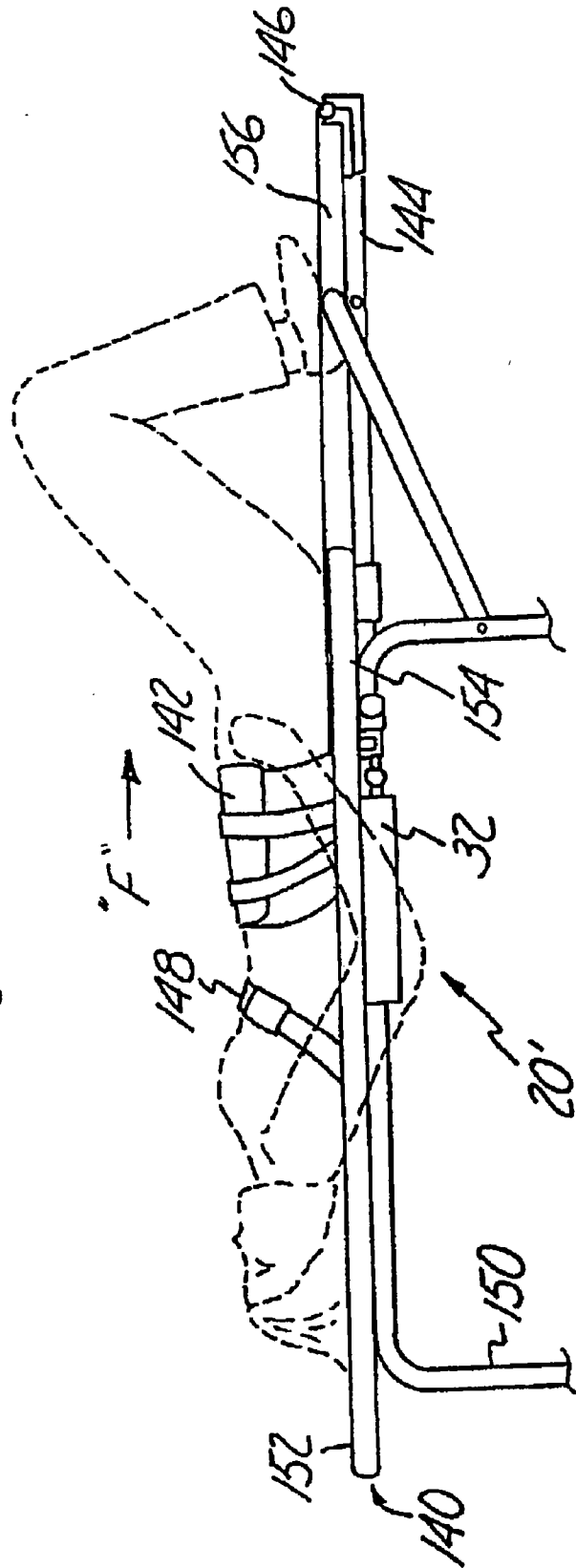
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Fig. 8



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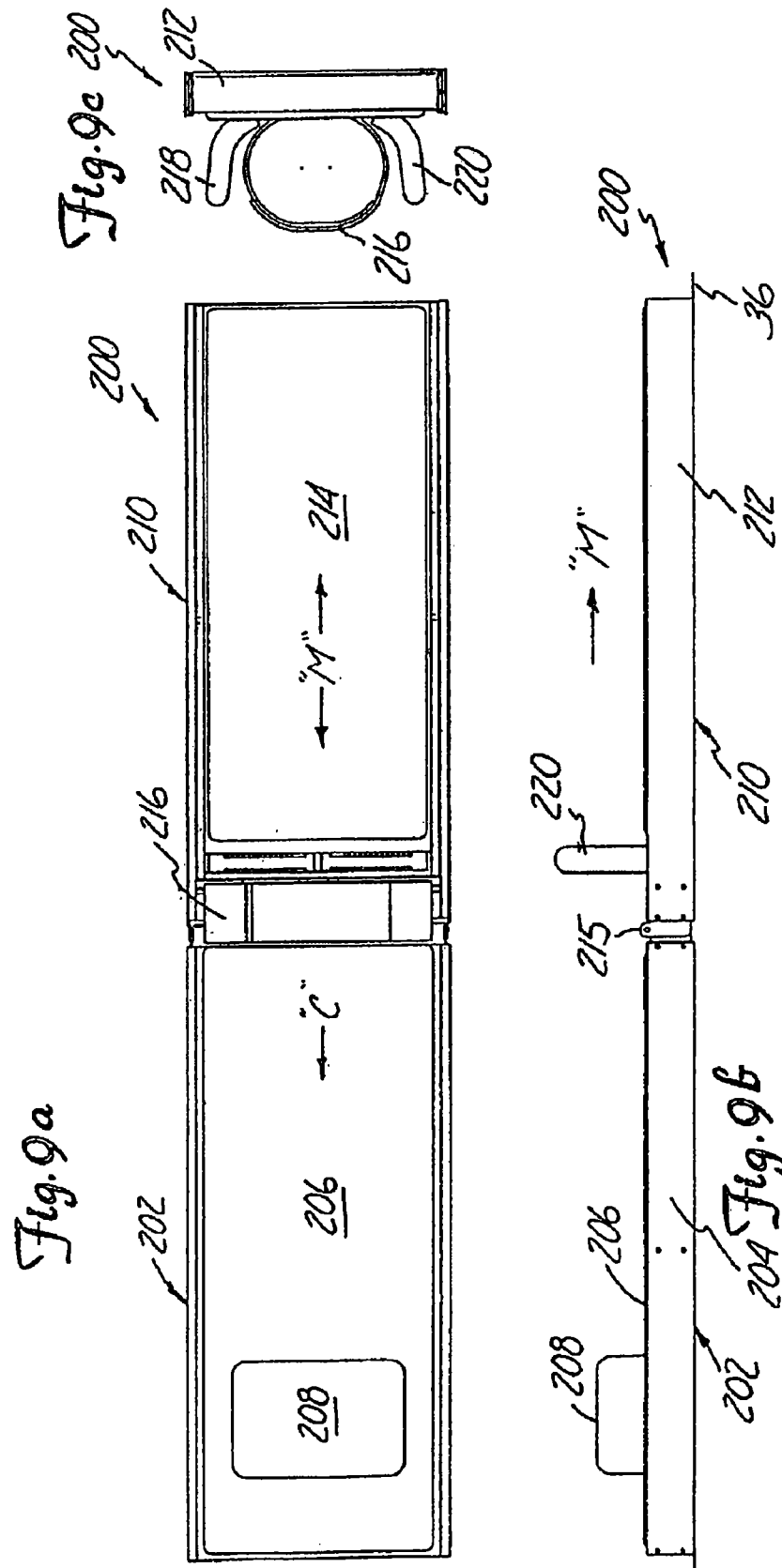


Fig. 10

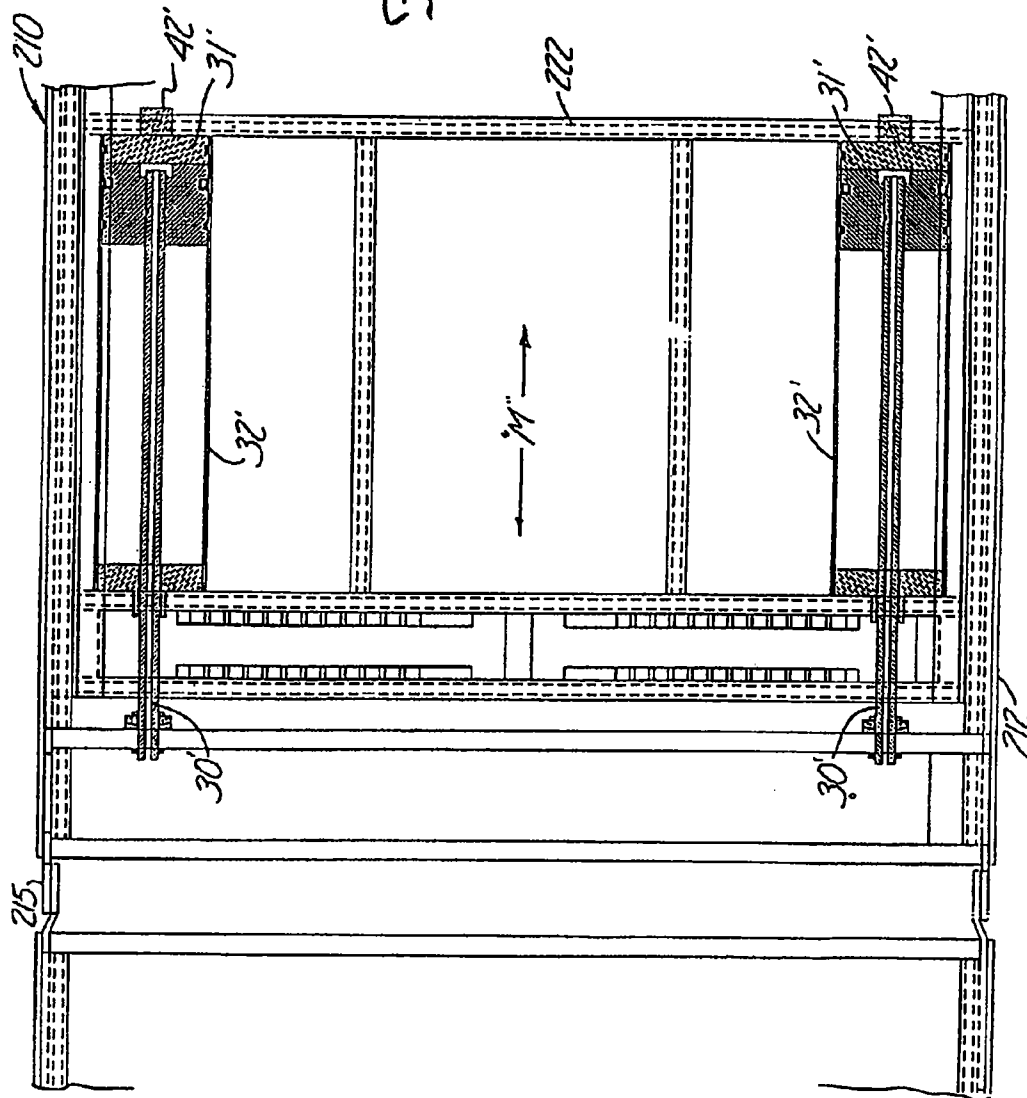
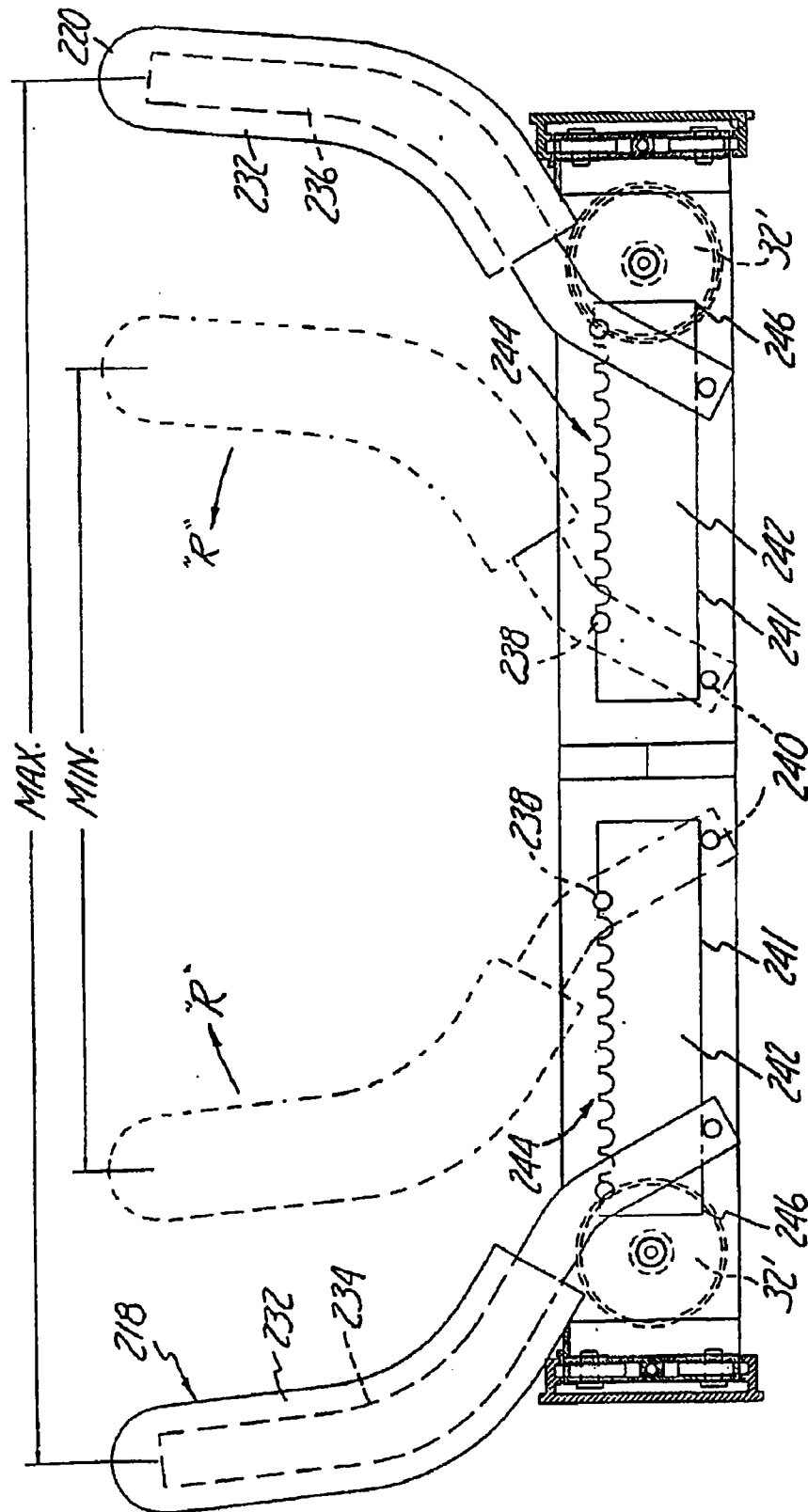


Fig. 11





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**PORTABLE CERVICAL TRACTION DEVICE****RELATED APPLICATIONS**

The present application is a continuation of U.S. patent application Ser. No. 08/817,444 filed Oct. 22, 1997, now U.S. Pat. No. 6,506,174 entitled Portable Traction Device (allowed), which is a continuation of PCT/US95/14217 filed Oct. 31, 1995, which claims priority to and is a continuation-in-part of U.S. patent application Ser. No. 08/334,189 filed Nov. 3, 1994 (abandoned).

**FIELD OF THE INVENTION**

The present invention is directed to a portable traction device powered by a pneumatic cylinder.

**BACKGROUND OF THE INVENTION**

Traction is widely used to relieve pressure on inflamed or enlarged nerves. While traction is applicable to any part of the body, cervical and lumbar or spinal traction are the most common. When correctly performed, spinal traction can cause distraction or separation of the vertebral bodies, a combination of distraction and gliding of the facet joints, tensing of the ligamentous structures of the spinal segment, widening of the intervertebral foramen, straightening of spinal curvature and stretching of the spinal musculature. Depending on the injury being treated, the traction component of physical therapy may require multiple sessions per week for a prolonged period of time.

Cervical traction requires a traction force up to approximately 222 N (50 lbs.). Lumbar traction typically requires force equal to half of the patient's bodyweight, or about 333-667 N (75-150 lbs.). The equipment necessary for performing traction, however, has typically been expensive and thus only available to a patient in a therapist's office.

Attempts to create a sufficiently low cost portable traction device for home use have thus far produced unsatisfactory results. A number of portable traction devices utilize pneumatic or hydraulic cylinders to create the traction force. Hydraulic cylinders have the disadvantage of the weight of the hydraulic fluid. Pneumatic cylinders with low pressure inputs typically can not maintain an adequate traction force for a sufficient period of time to be effective in a traction device. In an attempt to overcome this deficiency, some of these devices utilize an automatic pumping device triggered by a pressure sensing device to supply additional compressed air so that a constant level of traction force is maintained. These pump and sensor configurations add cost, weight and complexity to the traction device.

The air input pumps used on some traction devices also exhibit a number of shortcomings. For example, bulb-type air pumps produce relatively small input pressures. A small female patient can generate only about 483 kPa (7 psi) of pressure using a bulb-type pump. Consequently, small input pressure devices require large diameter cylinders to generate the necessary output traction forces. Larger diameter cylinders, when used with low pressure input devices, are more prone to leak, thereby further complicating the problem of maintaining a constant traction force for a prolonged period of time.

Therefore, what is needed is a low cost, light weight portable traction device utilizing a pneumatic cylinder which can maintain a traction force of an adequate magnitude for a prolonged period of time.

**SUMMARY OF THE INVENTION**

The present invention is directed to a portable traction device powered by a pneumatic cylinder. The present inven-

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tion is also directed to a pneumatic cylinder suitable for use in traction devices.

The portable traction device includes a support structure having a longitudinal axis and a carriage slidable along a portion of the support structure parallel to the longitudinal axis. The carriage including restraining mechanism for releasably restraining a portion of a patient's body to the carriage. A pneumatic cylinder includes a cylinder housing attached to the support structure. The cylinder housing contains a piston and piston rod. The piston rod is attached to the carriage for moving the carriage along the longitudinal axis relative to the support structure when pressurized air is injected into the pneumatic cylinder. The piston has at least one pressure activated seal extending circumferentially around the piston for engagement with an inside surface of the cylinder housing. A bicycle-style hand pump fluidly connected to the pneumatic cylinder is provided for injecting pressurized air into the cylinder.

In one embodiment, the portable traction device is configured for use as a portable, cervical traction device. The carriage may include a head support pad to receive a patient's head and a pair of opposing neck supports contoured and arranged to engage the occipital area of the patient's head when the head is on the head support pad. The neck supports are adjustably attached to the carriage to permit adjustment of the lateral separation therebetween. A head support strap may be provided for restraining the patient's head to the support pad.

In an alternate embodiment, the portable traction device is configured as a portable, lumbar traction device. The restraining mechanism may include a waist belt for releasably restraining the lower body of the user to the carriage. The support structure preferably includes counter traction restraining mechanism for restraining the upper body of the user to the support structure. Alternatively, the restraining mechanism includes a pair of opposing, laterally adjustable hip gripping supports arranged to engage the superior edge of the user's pelvis.

The piston has a diameter smaller than an internal diameter of the cylinder housing so that a gap is formed therebetween. The pressure activated seal may be a pair of pressure activated seals arranged circumferentially around the piston. The pressure activated seal is a generally V-shaped seal member arranged to expand when the air pressure in the pneumatic cylinder exceeds 13.8 kPa (2 psi).

In one embodiment, the pressure activated seal maintains a generally static traction force of greater than 111 N (25 pounds) for a period in excess of 10 minutes without additional pressurized air being injected into the cylinder. In an alternate embodiment, the pressure activated seal maintains a generally static traction force of greater than 200 N (45 pounds) for a period in excess of 20 minutes without additional pressurized air being injected into the cylinder.

The hand pump preferably includes a gauge indicating traction force and a pressure relief mechanism to manually release pressure in the pneumatic cylinder. In one embodiment, the operator rotates the gauge relative to the hand pump to release pressure from the cylinder. The cylinder preferably includes a pressure regulator to prevent the pressure in the pneumatic cylinder from exceeding a predetermined value. Alternatively, the pressure regulator may be located on the hand pump. The hand pump is capable of injecting at least 207 kPa (30 psi) of pressure to the pneumatic cylinder.

The present invention is also directed to the pneumatic cylinder and hand pump discussed above for use as the traction force generating apparatus on a portable traction device.



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## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view of a portable traction device;

FIG. 2 is a top view of the portable traction device of FIG. 1;

FIG. 3 is an end view of the portable traction device of FIG. 1 illustrating a laterally adjustable neck support;

FIG. 4 is a side view of a patient utilizing the traction device of FIG. 1;

FIG. 5 is a schematic illustration of an exemplary pneumatic cylinder for use with a portable traction device;

FIG. 6 is a top view of an exemplary air pump;

FIG. 7 is a side view of the exemplary air pump of FIG. 6;

FIG. 8 illustrates an exemplary portable, lumbar traction device;

FIGS. 9a-9c illustrate a top, front and end view of an alternate portable lumbar traction device;

FIG. 10 illustrates a pneumatic cylinder configuration for use with a portable, lumbar traction device; and

FIG. 11 illustrates a hip gripping device for a portable, lumbar traction device.

DETAILED DESCRIPTION OF THE  
PREFERRED EMBODIMENT

FIGS. 1 and 2 illustrate an exemplary portable, cervical traction device 20 in which a carriage 22 and slide portion 24 are allowed to move freely on a track 26 along a direction "S" (see also FIG. 3). The slide portion 24 includes a slide bracket 28 which engages with a piston rod 30 on a pneumatic cylinder 32 mounted underneath the track 26. A lateral adjustment mechanism 38, a head support pad 76, and a pair of V-shaped neck supports 50, 52 (see FIG. 3), are mounted to the carriage 22, which will be discussed in detail below. The pneumatic cylinder 32 is attached to the track 26 by an angle bracket 34. An air line 40 is attached to an air inlet 42 at one end of cylinder 32 for providing pressurized air to the cylinder 32. An alternate V-shaped neck support structure suitable for use in the present invention is disclosed in U.S. Pat. No. Re. 32,791 issued to Saunders on Nov. 29, 1988, which is hereby incorporated by reference.

The angle bracket 34 also serves the purpose of retaining the track 26 at an angle  $\alpha$  relative to a support surface 36. A removable stabilizer bracket 35 may optionally be added to prevent the angle bracket 34 from lifting off of the support surface 36 during use. A pad 37 preferably is placed over the angle bracket 34 for the comfort of the user. It will be understood that the length of the angle bracket 34 may be adjustable depending on the application of the portable traction device 20. For example, the angle bracket 34 may be of a telescoping constructions. It will also be understood that the slide portion 24 may engage with the track 26 in a variety of configurations, and that the present invention is not limited to the specific embodiment disclosed herein. The track 26, carriage 22, and slide portions 24 are preferably constructed of a lightweight, low cost material, such as, for example, aluminum, steel, high density plastic, or a variety of composite materials.

FIG. 3 is an end view of the lateral adjustment mechanism 38 on the carriage 22. Left and right neck supports 50, 52 form a V-shaped neck support structure that generally follows the contour of the base of the user's skull. The neck supports 50, 52 are attached to a pair of corresponding lateral slides 54, 56 on the carriage 22. The lateral slides 54, 56 are engaged with the threaded shaft 58 by a pair of

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coupler nuts 60, 62. The portion of the shaft 58 proximate coupler nut 60 has left-hand threads and the portion proximate coupler nut 62 has right-hand threads. The lateral position of the V-shaped neck supports 50, 52 is adjusted by turning the left and right knobs 70, 72. The neck supports 50, 52 are ideally positioned around the patient's head so that they contact and follow the contour of the occipital bone at the base of the patient's skull, while the back of the patient's skull rests on the head support pad.

FIG. 4 illustrates a patient 78 utilizing the portable traction device 20 on a support surface 36. It will be understood that the present portable traction device 20 may be used on a variety of support surfaces, such as for example, a floor, a table, or any other suitable surface. It will also be understood that the support surface 36 does not necessarily have to be horizontal and that it may be desirable to have an angled support surface for some types of traction. A support strap 77 may optionally be used to restrain the patient's head to the head support pad 76 during traction.

FIG. 5 is a schematic illustration of a single-acting pneumatic cylinder 32 for use with a present portable traction device. Piston 80 has a diameter "P" which is slightly smaller than the inside diameter "C" of the cylinder 32 so that a small gap 82 is formed between the piston 80 and inner surface 84 of cylinder wall 86. A pair of slots 88, 90 extending around the outside perimeter of the piston 80 contain a pair of pressure activated seals 92, 94. The seals 92, 94 are pre-shaped to form seal cavities 98, 100 facing upstream of the piston rod 30. It will be understood that the seals 92, 94 and seal cavities 98, 100 may be a variety of shapes.

The seals 92, 94 are arranged so that as pressurized air 91 enters the air inlet 42, and input chamber 96 is pressurized, a seal cavities 98, 100 are pressurized and the pressure activated seals 92, 94 are forced into engagement with the inside surface 84 of the cylinder wall 86. In the exemplary embodiment disclosed herein, approximately 13.8 kPa (2 psi) is required to engage the seals 92, 94 with the inside surface 84. Seal 94 is intended to capture blow-by air that passes the first seal 92. The small gap 82 between the cylinder wall 86 and the piston 80 permits generally uniform circumferential pressurization of the seals 92, 94 against the inside surface 84 around the entire circumference, thereby enhancing sealing capabilities. The pressure activated seal of the present pneumatic cylinder 32 is capable of maintaining a static traction force of greater than 111 N (25 lbs.) for a period in excess of 10 minutes, and preferably, a static tract on force of greater than 200 N (45 lbs.) for a period in excess of 20 minutes, without the need to supply additional pressurized air.

When the pressure in input chamber 96 is released, the seals 92, 94 disengage from the inside surface 84 and the piston 80 is allowed to move freely within the cylinder 32. The pneumatic cylinder 32 may include spring or other resilient compression member 102 around the piston rod 30 to urge the piston 80 back toward the air inlet 42 when the compressed air 91 is released. Alternatively, a spring (not shown) may be positioned between the slide portion 24 and the track 26. The compression member 102 preferably has a low spring forces so as to minimize the amount of force needed for the patient to activate the cylinder.

FIGS. 6 and 7 illustrate an exemplary air pump 120 for use with the present portable traction device 20. The air pump 120 has a T-handle 122 attached at one end by a pivot point 124. The T-handle 122 configuration offers ergonomic advantages over a standard straight pump handle.



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Alternatively, a straight handle may be substituted for the T-handle. An adjustable pressure regulator 126 may optionally be included in the pump 120 or cylinder 32 (see FIG. 1) so that over-pressure situations can be prevented. The other end of the air pump 120 includes a gauge 128, which preferably is calibrated to read the actual amount of traction force being provided to the patient, rather than pounds per square inch. The pump, handle and gauge may be formed as a singled piece by an injection molding process.

A manual pressure relief mechanism 130 is also located proximate the gauge 128 for relieving the pressure in the pneumatic cylinder 32 when the treatment period is completed. Alternatively, the pressure relief mechanism (not shown) may be operated by rotating the gauge 128. Air tube 40 is connected to the air pump 120 opposite the gauge 128. A variety of pressure regulator configurations may be used in the present invention. For example, the pressure gauge 128 may include an internal pressure regulator.

To use the portable, cervical traction device 20, it is placed on a suitable support surface 36. The left and right knobs 70, 72 are rotated to allow the neck of the user to fit easily between the left and right neck supports 50, 52. The slide portion 24 is moved down on the track 26 as far as possible by depressing pressure relief mechanism 130 (see FIG. 7) until cylinder 32 is at atmospheric pressure.

The back of the user is placed on the support surface 36 so that the neck is cradled by the neck supports 50, 52. The neck supports 50, 52 should initially contact the user in the mid cervical region, midway between the tip of the earlobe and the top of the shoulder. The knobs 70, 72 are turned until the neck supports 50, 52 are moved firmly against both sides of the neck. The user's head is secured to the head support pad 76 by the support strap 77. With the head support pad 76 under the shoulders, the user's head should be nearly aligned with the spine.

The user then slowly pumps air into the cylinder 32 using the air pump 120. The configuration of the pump 120 permits a patient to simultaneously view the gauge 128 and operate the pump, while inclined in the portable traction device 20. The gauge 128 allows the user to stay within the pressure/traction force guidelines provided by the health care provider. The patient increases the traction force by manually operating the pump 120 or decreases the traction force by manually pressing the pressure relief mechanism 130. The neck supports 50, 52 are properly positioned when there is solid contact at the base of the head and the supports 50, 52 are positioned near the tip of the ear lobes. When the treatment is complete, the traction force is released by pressing and holding the pressure relief mechanism 130 on the air pump 120.

FIG. 8 illustrates a portable, lumbar traction device 140 in which the pneumatic cylinder 32 is attached to a portable traction device 140. The portable, lumbar traction device 140 includes a frame 150 retaining a support surface 152. In a first embodiment, a pelvic belt 142 retains the patient's pelvis to a sliding portion 154, which slides along track 156. The pneumatic cylinder 32 mounted to the frame 150 is coupled to the sliding portion 154 so that the sliding portion 154 moves along the track 156, creating a traction force "F" when the cylinder 32 is pressurized. A counter traction belt 148 provides a passive counter traction force on the patient's lower rib cage. The pneumatic cylinder 32 preferably maintains a static traction force of greater than 445 N (100 lbs.) for a period in excess of 10 minutes, and preferably, a static traction force of greater than 890 N (200 lbs.) for a period in excess of 20 minutes, without the need to supply addi-

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tional pressurized air. It will be understood that two cylinders may be necessary to achieve a static traction force in excess of 445 N.

In a second embodiment, pelvic belt 142 is engaged with the pneumatic cylinder 32 by a cable 144 and pulley 146 configuration mounted at the foot of the portable traction device 140. Counter-traction belt 148 provides a passive counter traction force on the patient's lower rib cage to restrain the patient in a fixed position relative to the portable traction device 140. When the patient activates the pneumatic cylinder 32 as discussed above, the cable 144 is retracted, creating a traction force "F" on the waist belt 142 and the patient's pelvic region. In either of the above embodiments, the counter traction belt 148 may also be coupled to the pneumatic cylinder 32 to provide an active counter traction force in a direction opposite to "F" on the patient.

FIGS. 9a-9c illustrate an alternate embodiment of a portable, lumbar traction device 200 positioned directly on the support surface 36. Upper body support platform 202 includes a frame 204 supporting a support surface 206. A moveable head rest 208 is positioned on the surface 206. Lower body support platform 210 has a support surface 214 slidably engaged with frame 212. The surface 214 on the lower body support platform 210 slides in a direction "M" preferably about 0.15 meters under the force of a pair of pneumatic cylinders 32' (see FIG. 10). The upper and lower body support platforms 202, 210 are connected by a hinge 215 to facilitate shipping and storage of the lumbar traction device 200.

An adjustable rib gripping belt 216 is attached to the upper body support platform 202 to provide a passive counter traction force in a direction "C". A pair of laterally adjustable hip gripping supports 218, 220 are connected to the surface 214 so that they move in the direction "M" with the surface 214. The hip gripping supports 218, 220 are independently adjustable and curved to generally correspond to the shape of the user's waist, as will be discussed in connection with FIG. 11.

FIG. 10 illustrates a segment of the frame 212 of the lower body support platform 210. The piston rods 30' of the pneumatic cylinders 32' are engaged with the frame 210. Cylinder heads 31' are attached to sliding support structure 222 that supports surface 214. Introduction of pressurized air through the air inlet 42' moves the sliding support structure 222 and support surface 214 in the direction "M". The operation of the cylinders 32' is substantially as discussed above in connection with FIGS. 5-7. The pair of cylinders 32' maintain a static traction force of at least 890 N (200 lbs.) for a period in excess of 20 minutes, without the need to supply additional pressurized air.

FIG. 11 illustrates a hip gripping device 230 for use with the portable, lumbar traction devices 20' and 200 of the present invention. The hip gripping supports 218, 220 are shown in both the maximum and minimum lateral positions. In the exemplary embodiment illustrated in FIG. 11, the maximum and minimum lateral positions correspond to a distance of 0.50 m and 0.29 m, respectively. However, it will be understood that the hip gripping device may be modified to accommodate larger and smaller users.

The hip gripping supports 218, 220 include rigid curved members 234, 236 covered with padding material 232 for the comfort of the user. The curves generally follow the contour of the waist of the human body. Suitable padding material include high density foam, rubber or a variety of elastomeric materials. The rigid curved members 234, 236





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include a pin 238 positioned to engage with receiving slots 244 on the top of the track 242 and a pin 240 positioned to engage with the bottom surface 241 of the track 242. To adjust the hip gripping device 230, the user rotates one or both of the hip gripping supports 218, 220 in the direction "R" so that the pin 238 disengages from the slots 244. While in the rotated position, the hip gripping supports 218, 220 may be moved laterally along the track 242 to the desired location. Rotating the hip gripping supports 218, 200 in the direction opposite to "R" will engage the pin 230 with one of the slots 244. The hip gripping supports 218, 220 may be completely disengaged from the track 242 by moving the pin 240 past the ends 246 of the track 242 near the cylinders 32' and lifting the supports 218, 220 upward. It will be understood that the waist belt 142 of FIG. 8 may be substituted for the hip gripping device 230.

To use the portable, lumbar traction device 200, it is placed on a suitable support surface 36. The hip gripping supports 218, 220 are positioned to firmly, but comfortably, engage the waist of the user. The support surface 214 of the lower body support platform 210 is moved upward toward the upper body support platform 202 as far as possible by depressing the pressure relief mechanism 130 (see FIG. 7) until cylinders 32' are at atmospheric pressure.

The back of the user is placed on the support surface 206 so that the waist is cradled by the hip gripping supports 218, 220. The hip gripping supports should initially contact the user midway between the bottom of the rib cage and the top of the pelvis. The user's chest is secured to the support surface 206 of the upper body support platform 202 by the rib gripping belt 216. The head rest 208 should be placed under the user's head. The user then slowly pumps air into the cylinders 32' using the air pump 120, as discussed in connection with the portable, cervical traction device 20. The hip gripping supports 218, 220 are properly positioned when there is solid contact with the top of the pelvis.

The present invention has now been described with reference to the several embodiments thereof. It will be apparent to those skilled in the art that many changes can be made in the embodiments described without departing from the scope of the invention. Thus, the scope of the present invention should not be limited to the structures described herein, but only by structures described by the language of the claims and the equivalents of those structures. For example, the present portable traction device may be arranged in a variety of configurations to facilitate traction to any part of the body.

What is claimed is:

1. A cervical traction device comprising:

- a support structure having a track;
- a carriage having a slide bracket slidable along a portion of the track;
- a restraining mechanism adapted to releasably restrain a portion of a patient's body to the carriage;
- a pneumatic cylinder having a first end and a moveable piston rod at a second end, one of the pneumatic cylinder or the piston rod attached to the support structure and the other attached to the carriage, the pneumatic cylinder adapted to move the carriage along the track relative to the support structure when in a pressurized state, the pneumatic cylinder maintaining a generally static traction force for a period in excess of 10 minutes when in the pressurized state without additional pressurized air being supplied; and
- a hand pump fluidly connected to the pneumatic cylinder and adapted to inject pressurized air into the pneumatic

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cylinder, the hand pump having a handle moveable relative to a body portion to injecting at least 138 kPa (20 psi) of pressure into the pneumatic cylinder.

2. The apparatus of claim 1 wherein the carriage comprises a head support pad to receive a patient's head and the restraining mechanisms comprises a pair of opposing neck supports contoured and arranged to engage the occipital area of the patient's head when the head is on the head support pad.

3. The apparatus of claim 1 comprising a pair of opposing neck supports adjustably attached to the carriage to permit adjustment of the lateral separation therebetween.

4. The apparatus of claim 1 wherein a piston attached to the piston rod has a diameter smaller than an internal diameter of a cylinder housing so that a gap is formed therebetween.

5. The apparatus of claim 4 wherein the gap is capable of permitting generally uniform circumferential pressurization of seals against the inside surface of the cylinder housing.

6. The apparatus of claim 1 comprising at least one pressure activated seal in the pneumatic cylinder extending circumferentially around a piston, the pressure activated seal movable between a relaxed position and an extended position so the pressure activated seal engages an internal surface on the pneumatic cylinder when the pneumatic cylinder is in the pressurized state for engagement with an inside surface of a cylinder housing when in the pressurized state.

7. The apparatus of claim 6 wherein the at least one pressure activated seal comprises a generally V-shaped seal member arranged to expand when the air pressure in the pneumatic cylinder exceeds 13.8 kPa (2 psi).

8. The apparatus of claim 1 wherein the generally static traction force of about 111 N (25 pounds).

9. The apparatus of claim 1 wherein the generally static traction force of about 200 N (45 pounds).

10. The apparatus of claim 1 wherein the pneumatic cylinder is capable of maintaining a generally static traction force a period in excess of 20 minutes without additional pressurized air being injected into the cylinder.

11. The apparatus of claim 1 wherein the pump further includes a gauge indicating traction force.

12. The apparatus of claim 1 wherein the pneumatic cylinder includes at least one pressure regulator to prevent the pressure in the pneumatic cylinder from exceeding a predetermined value.

13. The apparatus of claim 1 wherein the pump includes a pressure relief mechanism to manually release pressure in the pneumatic cylinder.

14. A cervical traction device comprising:

- a support structure having a track;
- a carriage having a slide bracket slidable along a portion of the track;
- a pair of opposing neck supports adjustably attached to the carriage to permit adjustment of the lateral separation therebetween;
- a pneumatic cylinder having a first end and a moveable piston rod at a second end, one of the ends of the pneumatic cylinder attached to a support structure and the other end attached to the carriage, the pneumatic cylinder adapted to move the carriage along the track relative to the support structure when in a pressurized state;



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at least one pressure activated seal in the pneumatic cylinder extending circumferentially around a piston, the pressure activated seal movable between a relaxed position and an extended position so the pressure activated seal engages an internal surface on the pneumatic cylinder when the pneumatic cylinder is in the pressurized state for engagement with an inside surface of a cylinder housing when in the pressurized state, the pneumatic cylinder maintaining a generally static traction force for a period in excess of 10 minutes when in the pressurized state without additional pressurized air being supplied; and

a hand pump fluidly connected to the pneumatic cylinder and adapted to inject pressurized air into the pneumatic cylinder, the hand pump having a handle moveable relative to a body portion to injecting at least 138 kPa (20 psi) of pressure into the pneumatic cylinder.

15. A system comprising a pneumatic traction force generating apparatus and a portable cervical traction device, the portable cervical traction device having a carriage with a slide bracket slidable along a portion of a track on a support structure, the pneumatic traction force generating apparatus comprising a pneumatic cylinder attachable to the support structure for moving the carriage relative to the support structure when the pneumatic cylinder is in a pressurized state, the pneumatic cylinder having at least one pressure activated seal extending circumferentially around a piston, the pressure activated seal movable between a relaxed position and an extended position so the pressure activated seal engages an internal surface on the pneumatic cylinder when the pneumatic cylinder is in the pressurized state, the pneumatic cylinder maintaining a generally static traction force for a period in excess of 10 minutes when in the pressurized state without additional pressurized air being supplied.

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16. A cervical traction device comprising:

a support structure having a track;

a carriage having a slice bracket slidable along a portion of the track;

a restraining mechanism adapted to releasably restrain a portion of a patient's body to the carriage;

a pneumatic cylinder having a first end and a moveable piston rod at a second end, one of the pneumatic cylinder or the piston rod attached to the support structure and the other attached to the carriage, the pneumatic cylinder adapted to move the carriage along the track relative to the support structure when in a pressurized state, the pneumatic cylinder maintaining a generally static traction force during a treatment period when in the pressurized state without additional pressurized air being supplied; and

a hand pump fluidly connected to the pneumatic cylinder and adapted to inject pressurized air into the pneumatic cylinder.

17. The apparatus of claim 16 wherein the pump further includes a gauge indicating traction force.

18. The apparatus of claim 16 wherein the pneumatic cylinder includes at least one pressure regulator to prevent the pressure in the pneumatic cylinder from exceeding a predetermined value.

19. The apparatus of claim 16 wherein the pump includes a pressure relief mechanism to manually release pressure in the pneumatic cylinder.

20. The apparatus of claim 16 wherein the hand pump has a handle moveable relative to a body portion to inject at least 138 kPa (20 psi) of pressure into the pneumatic cylinder.

21. The apparatus of claim 16 wherein the carriage comprises a pair of opposing neck supports contoured and arranged to engage a patient's head.

\* \* \* \* \*



**CERTIFICATE OF SERVICE**

I hereby certify that on this 12th day of July, 2007, I electronically filed the foregoing documents, **IMPAX'S RESPONSE TO WYETH'S CITATION OF SUBSEQUENT AUTHORITY IN SUPPORT OF ITS MARKMAN BRIEFING** with the Clerk of the Court using CM/ECF which sent notification of such filing to the following:

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Additionally, I hereby certify that on the same date, the foregoing document was served as indicated below:

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